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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,441	01/21/2004	Bruce Lessey	24739-2101G	5177

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,441	LESSEY, BRUCE	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of the species electrophoresis for the detection of the β_3 integrin subunit in the reply filed on August 12, 2004 is acknowledged.

Claims 1-16 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant has claimed a method for diagnosing infertility in a mammal by detecting the presence and level of β_3 integrin in a sample of endometrium without reciting a detection agent or procedure for detection except in dependent claims 15 and 16. As such, apart from claims 15 and 16, the claims are read to include any means or agent to detect β_3 integrin.

Applicant has disclosed in the description of preferred embodiments and in the examples that a monoclonal antibody is used to detect the β_3 integrin subunit. Applicant discloses on page 9, lines 13-14 of the specification, that other glycoprotein detection methods are known in the art, but the techniques enumerated on page 9, lines 14-17 of the specification, relate to either the labeling or the detection of antibodies. As such, the specification does not describe the use of reagents other than antibodies in the claimed invention. Therefore, Applicant is claiming a broad genus of detection methods when only the species of antibody detection has been disclosed.

MPEP section 2163.05 clearly states that when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Claims 15 and 16 recite specific reagents and techniques for detecting the β_3 integrin subunit, but only electrophoresis, Northern blotting, and molecular weight do not necessarily involve the use of antibodies. It is noted that electrophoresis is required to perform Western blotting, and that Western blotting will allow a determination of molecular weight. Alternatively, electrophoresis could be followed by staining with Coomassie™ Blue R250, for example, to allow a determination of molecular weight. Electrophoresis also encompasses the more precise technique of 2D electrophoresis where proteins are separated based upon charge and apparent molecular weight rather than just apparent molecular weight. Detection by Northern blotting requires the possession of a labeled nucleic acid probe that will specifically bind β_3 integrin subunit mRNA.

Potential methods of detecting the β_3 integrin subunit that are not claimed are the use of ligand-receptor assays since the ligands for defined combinations of β_3 and α subunits are known, and PCR amplification of mRNA fragments.

As indicated above, there is substantial variation within the genus of ways to detect the β_3 integrin subunit. The ability to detect a molecule using nucleic acid probes, by PCR, by using monoclonal antibodies to detect a protein, and by using receptor-physiological ligand receptor assays are substantially different from one another. All of these techniques have a multitude of assay permutations, none of which are contemplated by Applicant with regard to the non-disclosed methods of detection. One cannot describe what one has not conceived.

Since there is high variability amongst the genus of detection methods of the claimed invention, and Applicant has disclosed only a limited amount of the genus, the claimed invention does not have written support within the originally filed specification. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, which make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between

function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus.

4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the detection of the β_3 integrin subunit using a monoclonal antibody, does not reasonably provide enablement for the detection of the β_3 integrin subunit by any technique. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has disclosed that the present invention is directed to methods of detecting the receptivity of endometrium tissue, diagnosing fertility, and preventing embryo implantation using a monoclonal antibody that specifically binds the β_3 integrin subunit (page 2, line 29 to page 3, line 30 of the instant disclosure). The disclosed description of preferred embodiments and the examples both only make use of a monoclonal antibody in detecting the β_3 integrin subunit.

Applicant has claimed a method for diagnosing infertility in a mammal by detecting the presence and level of β_3 integrin in a sample of endometrium without reciting a detection agent or procedure except in dependent claims 15 and 16. As such, apart from claims 15 and 16, the claims are read to include any means or agent to detect β_3 integrin.

The specification provides does not appear to provide working examples or guidance on how any other molecule can be used to specifically detect β_3

expression in endometrium other than through the use of monoclonal antibodies. Applicant discloses that other glycoprotein detection methods (page 9, lines 13-14 of the specification) are known in the art, but the discussion of such techniques is limited to antibody-based methods. Additionally, Applicant's invention is the specific detection of β_3 expression as it changes through the estrus cycle, not the detection of generalized glycoprotein expression. Without additional guidance or working examples that detect the β_3 integrin subunit by non-antibody based techniques, one of skill in the art would not be able to practice the claimed invention without an undue amount of experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claims 1-14 the omitted steps are the lack of an agent to be used in the step of detecting the presence of the β_3 integrin subunit. Incorporation of the detection methods listed in claims 15 and 16 into the base claim 1 would help to obviate this rejection.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 14-19, and 28 of U.S. Patent No. 6,733,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16

are broader in scope and would encompass claims 3, 4, 14-19, and 28 of U.S. Patent No. 6,733,979.

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-17 of U.S. Patent No. 5,279,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 5,279,941 are species claims to the instantly filed claims and therefore anticipate them.

9. No claims are allowable

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 29, 2004

Patrick J. Nolan, Ph.D.
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9/29/04